

INFORMATION PAPER

MILVAX - VHCN
12 December 2013

SUBJECT: Meningococcal Disease and Meningococcal Vaccines

1. Purpose. To describe meningococcal disease and the vaccines to prevent it.

2. Facts

a. Microbiology. *Neisseria meningitidis*, or meningococcus, is an aerobic, gram-negative diplococcus, closely related to *N. gonorrhoeae* and to several nonpathogenic *Neisseria* species, such as *N. lactamica*. *N. meningitidis* has both an inner and outer membrane, separated by a cell wall. The outer membrane contains several protein structures that enable the bacteria to interact with the host cells as well as perform other functions. The outer membrane is surrounded by a polysaccharide capsule that protects the organism from phagocytosis and complement-mediated lysis. There are thirteen distinct serogroups, which are based on the characteristics of the polysaccharide capsule.

b. Disease. *N. meningitidis* colonizes mucosal surfaces of the nasopharynx and is transmitted through direct contact with respiratory droplet secretions from infected individuals and asymptomatic carriers. Humans are the only host. Meningococcal disease can be caused by a virus or bacterium and is a serious health threat, causing meningitis (inflammation of membranes around the brain and spinal cord), or blood infections (meningococcemia). Treatment varies, dependent on the cause and severity of illness. Viral meningitis is generally less severe and resolves without specific treatment. Bacterial meningitis can be extremely severe resulting in brain damage, hearing loss, or learning disability. For bacterial meningitis, it is important to know which type of bacteria is causing the meningitis because antibiotics can prevent some types from spreading and infecting other people. Common symptoms in individuals aged 2 years and older, which develop over several hours, or can take 1 to 2 days, include high fever, headache, and stiff neck. Other symptoms include nausea, vomiting, confusion, sleepiness, and discomfort looking into bright lights. In newborns and small infants, the classic symptoms may be difficult to detect. The infant may appear slow, inactive, and irritable; experience vomiting, or loss of appetite. As the disease progresses, individuals of any age may develop seizures. Meningococcal disease can be disfiguring or disabling (i.e., limb amputations, hearing loss, brain damage) in up to 20% of those who recover.

c. Epidemiology. Meningococcal disease occurs worldwide in both endemic and epidemic form. Despite the use of effective antibiotics, meningococcal disease still results in death for 10% to 14% of those who become ill. There are 13 serotypes of meningococcal bacteria. Serotype A disease occurs primarily in Africa (in the "meningitis belt") and Asia; serotype B accounts for more than 50% of meningococcal disease in infants aged 1 year and younger; and serotypes C, Y, and W-135 cause more than 75% of illness in persons aged 11 years and older. Serious (also called invasive) meningococcal disease occurs most often in infants younger than 1 year of age and surges a second time in adolescence. High-risk groups include college freshmen and military trainees living in dormitories (likely due to crowded living conditions), people with immune deficiencies, travelers to areas where the disease is endemic (sub-Saharan Africa), and people who do not have a spleen or whose spleen is not functioning (e.g., sickle-cell anemia).

d. Vaccines. Four vaccines are licensed in the U.S. to prevent meningococcal disease.

(1) Menomune® (MPSV4) produced by sanofi pasteur is a quadrivalent polysaccharide vaccine for serotypes A/C/Y/W-135. The diluent for the multi-dose vial contains thimerosal as a preservative. Vial stoppers contain latex.

(2) Menactra® (MenACWY-D) produced by sanofi pasteur is a quadrivalent polysaccharide-protein diphtheria toxoid conjugate vaccine for serotypes A/C/Y/W-135. Single dose syringes are both thimerosal and latex free. Vial stoppers contain latex.

(3) Menveo® (MenACWY-CRM) produced by Novartis is a quadrivalent polysaccharide-protein diphtheria CRM 197 conjugate vaccine for serotypes A/C/Y/W-135. Menveo® components must be reconstituted, and consists of a vial of liquid MenCYW-135 conjugate that is combined with a vial of Men A lyophilized powder. The product is both thimerosal and latex free.

(4) Menhibrix® (Hib-MenCY-TT) produced by GlaxoSmithKline is a combination vaccine for serogroups C and Y and Haemophilus influenza type b. Menhibrix® is supplied as a single-dose vial of lyophilized vaccine that is reconstituted with the accompanying vial of saline diluent. The product is both thimerosal and latex free.

e. Immunization. ACIP recommends routine vaccination for the following groups: adolescents aged 11-18 years (a single dose of vaccine should be administered at age 11 or 12 years, with a booster dose at age 16 years for persons who receive the first dose before age 16 years); persons aged greater than or equal to 2 months at increased risk for meningococcal disease (i.e., anatomical or functional asplenia, complement component deficiency); special populations such as unvaccinated or incompletely vaccinated first-year college students living in resident halls; and persons aged greater than or equal to 9 months who travel or reside in countries in which meningococcal disease is endemic. Review individual product package inserts for age, dosing schedule and booster dose requirements. See ACIP recommendations for vaccination of persons in special populations and those at increased risk for meningococcal disease.

(1) Menomune® is licensed for persons aged 2 years and older and is administered as a single 0.5-mL subcutaneous injection.

(2) Menactra® is licensed for persons between 9 months and 55 years of age and is administered as a single 0.5-mL intramuscular injection.

(3) Menveo® is licensed for persons aged 2 to 55 years and is administered as a single 0.5 mL intramuscular injection after reconstitution.

(4) Menhibrix® is licensed for use in children aged 6 weeks through 18 months. Four doses (0.5 mL each) are given by intramuscular injection at 2, 4, 6, and 12 through 15 months of age. First dose may be given at 6 weeks of age.

f. Cautions. Meningococcal vaccine should not be administered to persons with a history of serious allergic reaction to a previous dose or to any component of the vaccine. Immunize pregnant women only if the benefit clearly outweighs the risk. ACIP does not consider a history

of Guillain-Barre Syndrome (GBS) to be a contraindication or precaution for vaccination. See individual product package inserts for a full list of precautions to meningococcal vaccination.

g. Adverse Events. Reported adverse events were similar after immunization for all vaccines and include fever, injection-site reactions (e.g., soreness, redness), headache, fatigue, myalgia, malaise, nausea and drowsiness and diarrhea in children. All healthcare personnel administering vaccinations should be aware of the potential for syncope after vaccination, especially among adolescents, and should take appropriate measures to prevent potential injuries. See individual product package inserts for additional information concerning serious adverse events associated with meningococcal vaccines.

h. DoD Policy. Meningococcal immunization is mandatory for basic trainees and cadets at Service academies within the first two weeks of training. Immunize personnel traveling to sub-Saharan Africa, and other countries as recommended by ACIP.

3. References.

a. Centers for Disease Control and Prevention. Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2013. *MMWR* 2013; 62(RR02); 1-22.

b. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by MILVAX - VHCN: www.vaccines.mil/meningococcal

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